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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,760	09/27/2005	Anders Ljunggren	133087.09001	3784

52286 7590 03/26/2008

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EXAMINER	
THOMAS, TIMOTHY P	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
03/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,760	LJUNGGREN ET AL.	
	Examiner	Art Unit	
	TIMOTHY P. THOMAS	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11 and 14-20* is/are pending in the application.

4a) Of the above claim(s) *14-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11 and 17-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/6/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 1/3/2008 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

2. Applicant's arguments filed 1/3/2008 with respect to the rejection of claims 11-13 and 17-20 under 35 USC 112, 2nd paragraph have been fully considered but they are not persuasive:

Claims 11 and 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Although applicant has stated the intention of the claim is that an angiotensin II type 1 receptor antagonist "alone" does not exclude other non-active ingredient substances (i.e., "alone" is used with respect to which active agent(s) are present); this is not persuasive: it is still considered that the claim recitation of "alone" in the first embodiment of the claim can be interpreted as the administration of only the selected drug, i.e., without diluents, excipients, etc., or alternatively “only” can be read considering which active ingredient(s) is present. It is recommended that applicant amend “alone” in line 3 of claim 11 to a phrase, such as “as the only active agent”,

which would clarify which component is present in the first embodiment of the method in a manner consistent with applicant's arguments, and overcome the rejection.

3. Applicant's arguments with respect the rejections under 35 USC 112, 1st paragraph, enablement and written description rejections; and the rejections under 35 USC 102 have been considered but are moot in view of the new ground(s) of rejection.

The rejections have been withdrawn due to the claim amendments. The prior art rejections are withdrawn because the claim amendment removes the compound specie, candesartan cilesetil (a salt of I:5), from the claims; the revious rejections were based on this specie. The prior art rejection(s) that follow, are required to reject claims based on compound species that remain.

Claim Rejections - 35 USC § 102 & 103

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 11 and 17-20 are rejected under 35 U.S.C. 102(b) as anticipated by Eide et al. (US 5,962,500; 1999) or, in the alternative, under 35 U.S.C. 103(a) as obvious

over Eide et al. (US 5,962,500; 1999) and Terashita et al. (US 2006/0069133 A1; cited in previous Office Action).

Eide teaches imidazole compounds that are angiotensin II antagonists for the improvement of insulin sensitivity alone or in conjunction with the treatment of hypertension (abstract); instant compound I:2 (also known as EXP-3174) is taught as an example compound (col. 18, Example 2); ordinary dose ranges include 10-100 mg (col. 28, lines 11-13). Treatment of "insulin sensitivity" was a previous name for metabolic syndrome (see National Library of Medicine-Medical Subject Headings; "Metabolic Syndrome X", http://www.nlm.nih.gov/cgi/mesh/2008/MB_cgi?mode=&index=19750&field=all&HM=&II=&PA=&form=&input= ; accessed online 3/21/2008, which indicates Metabolic Syndrome X was previously known as Insulin Resistance from 1992-2001); which is reflected by Eide's teaching of the relationship between insulin resistance, cardiovascular disease, hypertension, obesity and glucose intolerance (col. 4, lines 19-30). Inherent in the teaching of EXP-3174 for treatment of insulin sensitivity would be treatment of metabolic syndrome. On the other hand, it might be argued that Eide does not teach all of the factors to indicate metabolic syndrome. In such a view Eide would not be considered to disclose the treatment of metabolic syndrome. Terashita teaches angiotensin II antagonistic compounds can be used in the treatment of Syndrome X (metabolic syndrome; abstract; claims 2-3; paragraph 0115). It would have been obvious to one of ordinary skill in the art to apply the method of treating insulin sensitivity taught by Eide for the treatment of metabolic syndrome or to substitute EXP-

3174 in the treatment of Syndrome X taught by Terashita. The motivation would have been the usefulness of different compounds with the same art-recognized activity in treatment of metabolic syndrome; or the art recognized substitution of one compound for another with the same art-recognized activity.

Conclusion

7. No claim is allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY P. THOMAS whose telephone number is (571)272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Timothy P Thomas/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614